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**REMARKS**

**Introductory General Remarks**

Applicants respectfully submit the instant Reply in response to the Office Action mailed 3 November 2003. Applicants respectfully request reconsideration of the above-identified application.

In the Office Action claims 40-79 stand pending, with claims 40-77 rejected and claims 78, 79 withdrawn from consideration by the Examiner. In this Reply, Applicants cancel claims 53, 78, and 79 (without prejudice or disclaimer as to the subject matter thereof), amend claims 40-43, 45-48, 50, 52, 54-72, 73-74 and 76-77. Applicants respectfully request entry and favorable consideration of the amendments and remarks contained herein.

Applicants again respectfully assert that the single reference relied upon by the Examiner, U.S. Pat. No. 6,059,601 issued to Hirai et al. ("Hirai"), essentially represents non-analogous prior art. That is, Hirai purportedly discloses an improved apparatus for *temporarily connecting* a mass termination connector for computer peripherals and the like wherein said apparatus has a reduced connector thickness.

In contrast, the present invention (as originally claimed, and, more particularly, as amended herein) does not contemplate any of the structure or methods of objects allegedly addressed by Hirai. Indeed, the presently claimed invention relates to the field of implantable medical devices and, more particularly, to improved methods and apparatus for sealingly and permanently coupling a plurality of elongated conductors to an implantable medical device.

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Thus, claims 40-79 are again herein presented for examination on the merits. Favorable consideration of said amended claims is earnestly solicited so that same may pass to timely issuance as U.S. Letters Patent.

**A. The Objection to the Drawings**

The Examiner objected to the drawings because allegedly certain claimed features were not depicted in the drawings. However, the Examiner recited *canceled claims 13 and 24* as reciting the offending subject matter. First of all, Applicants suggest that a claim limitation regarding a "plating material" (over a base metal) is inherently included when a base metal is depicted. Likewise, Applicants suggest that a first environment *within the housing* and a second environment *outside the housing* is also inherently included in any drawing that depicts any structure having an aperture, blind hold, bore, and the like. With respect to the "environments" Applicants aver that Figure 1, 12, 13A, and 13B all depict structures wherein said environments are clearly depicted. Therefore, Applicants suggest that no proposed drawing correction or corrected drawings are required. In addition, Applicants have amended the claims that now correspond to claims 13, 19-21 and 24 to render them in such form that no claim limitation can be construed as not depicted in the drawings.

**B. Claim Objections**

Claims 40, 45, 48, 54, 64, 66, and 77 are objected to for informalities.

Applicants herewith amend said claims to cure said informalities and thank the Examiner for assisting in curing the claims of said informalities.

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**C. Claim Rejections Under 35 U.S.C. §112, second paragraph**

In the Office Action claims 71, 60, 59 and 15 [sic] were rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention. Since claim 15 has been canceled previously and the detailed reasons for this rejection recite "claim 45" Applicants treat this rejection as being lodged against claims 45, 59, 60 and 71.

Applicants respectfully assert that these claims all employ the open-ended transitional phrase "comprising" and as such, are construed as including all limitations affirmatively recited and can include any other feature, component, system, sub-system and the like that is compatible with the affirmative claim limitations. In the case of independent claim 45 and claim 59 depending therefrom, Applicants assert that complete compatibility exists. That is, claim 45 recites "an apparatus for permanently connecting electrically-conducting components of an implantable medical device" (or "IMD). Claim 59 merely limits the claimed IMD to a select subset of IMDs. Therefore, complete consistency and compatibility exists as between the subject matter claimed by claims 45 and 59. By the same token, independent claim 60 recites "a feedthrough arrangement" within an IMD. Claim 71, which depends indirectly upon claim 60 (via claim 70) merely recites a select subset of IMDs. Thus, the claimed subject matter of these claims is entirely consistent and given the transitional phraseology employed, Applicants suggest that same cannot reasonably be objected to by the Examiner.

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**D. Claim Rejections Under 35 U.S.C. §102**

Claims 40, 41, 43-48, 50, 51, 53, 54, and 56 stand rejected over Hirai. Since claim 53 stands canceled without prejudice following entry of the instant Reply, Applicants suggest that no response to said rejection is required.

In general, the remarks regarding Hirai hereinabove are hereby cross-referenced and incorporated as if again fully set forth herein.

Applicants respectfully traverse the rejections as enumerated hereinbelow.

Although Applicants do not agree that Hirai represents analogous art susceptible of application against the present claims, Applicants herein directly amend claims 40, 41, 43, 45-48, 50, 51, 54, and 56 (although claim 44 stands amended due to amendment to independent claim 40 from which claim 44 depends). That is, because said amendments were deemed desirable and/or convenient, Applicant amended said claims such that in no manner could Hirai be interpreted as an anticipatory reference regarding the claims. As understood by Applicants and the Examiner, "[a] single prior art reference anticipates a patent claim if it expressly or inherently describes each and every limitation set forth in the patent claim." Trintec Indus. Inc. v. Top-U.S.A. Corp., 63 USPQ2d 1597, 1599 (Fed. Cir. 2002). "Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art." Id. Independent claims 40 and 45 both recite limitations not found expressly or inherently in Hirai. As such, the rejection based solely upon Hirai stands traversed *per se*. Accordingly, the Examiner should properly withdraw this ground of rejection.

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**E. Claim Rejections Under 35 U.S.C. § 103**

In the Office Action, the Examiner rejected claims 49, 59-61, 63-65, 67, 70-71, 72-75 and 77 under 35 U.S.C. § 103(a) as being unpatentable over a *single* reference, Hirai, as applied hereinabove. Applicants again cross-reference and incorporate by reference the remarks regarding Hirai hereinabove.

In connection with combining references to support an assertion of obviousness, it is well established that the Examiner bears the burden of establishing a *prima facie* case of obviousness. In re Oetiker, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). In doing so, the Examiner must determine whether the prior art provides a "teaching or suggestion to one of ordinary skill in the art to make the changes that would produce" the claimed invention. In re Chu, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995). A *prima facie* case of obviousness is established only when this burden is met.

The burden is still on the Examiner even when the Examiner relies upon a single reference. "Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference."

In re Kotzab, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000).

In the case of In re Lee, 61 USPQ2d 1430 (Fed. Cir. 2002), the Federal Circuit stated: "This factual question of motivation is material to patentability, and [can] not be resolved on subjective belief and unknown authority." *Id.* at 1434. Determination of patentability must be based on evidence, *id.* at 1434, and the Examiner provided none: no references pertaining to aggregation or averaging were cited, no official notice was taken, no evidence of any kind was presented. The Examiner's failure to present an evidentiary basis for the decision is clearly a legal error. *Id.* Assertions such as

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"common knowledge and common sense," even if assumed to derive from the Examiner's expertise, are not evidence, and conclusory statements do not fulfill the Examiner's obligation to make an evidentiary record. Id. at 1434-35; In re Dembiczak, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

If indeed the elements were known in the art, then the Examiner ought to present evidence to support that conclusion. In re Lee, 61 USPQ2d at 1435 ("[W]hen they rely on what they assert to be general knowledge to negate patentability, that knowledge must be articulated and placed on the record."). The failure to do so renders the Examiner's rejection arbitrary, capricious and unreasonable. See id. at 1434. The Examiner may not arbitrarily, capriciously and unreasonably deny a claim by a mere declaration of obviousness without a supporting evidentiary record.

The Examiner presented no evidence of any suggestion or motivation to modify Hirai to arrive at the claimed invention. Nor has the Examiner presented any evidence that the recited elements are known in the art. The record consists exclusively of conclusory statements by the Examiner, which are not evidence and which cannot support rejections under 35 U.S.C. § 103.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 38-46 (and 54-52 and 70-78) under 35 U.S.C. § 103(a). Withdrawal of this ground of rejection is hereby earnestly and respectfully requested.

With respect to the individual claims rejected solely on the basis of Hirai, and as a procedural matter from the outset, Applicants note that while claim 49 is listed as one of the rejected claims, no rationale was included in the office action supporting the

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alleged rejection. Accordingly, claim 49 is not amended herein and Applicants respectfully suggest the Examiner indicate the allowability of said claim as no *prima facie* obviousness or any other ground of rejection stands opposed to the patentability of claim 49.

Of the remaining claims rejected *solely* on the basis of Hirai under 35 U.S.C. §103, only claim 60 was individually addressed. Applicants respectfully assert that with respect to these claims and this ground of rejection the Examiner has failed to lodge a *prima facie* obviousness rejection and as such, the rejection cannot stand. Accordingly, the Examiner should properly withdraw this ground of rejection.

The Examiner simply declared that "Hirai discloses *substantially* the claimed invention except for apparatus being a component of an implantable medical device" (or "IMD"). Applicants suggest that the Examiner used the term "substantially" because certain claim limitations contained in the pending claims are not found, suggested, taught or depicted in Hirai. Nevertheless, the Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hirai "to use the structure of Hirai as a component of different electrical devices, such as an implantable medical device, to complete an electrical connection within the electrical device."

With respect to claim 60, the preamble of claim 60 has been amended to recite that the "apparatus for permanently connecting electrically-conducting components of an implantable medical device so that deployable medical electrical leads can be coupled thereto." Applicants suggest that the Examiner has, in general, misconstrued the "housing" element. That is, it appears as though the Examiner has construed

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"housing" to include what is commonly referred to as a "header" or "connector module" of an implantable medical device. This is incorrect. The housing described and depicted in the instant application is a discrete set of electrically insulating members that mechanically interlock to retain each of a plurality of discrete spaced-apart electrically conducting bonding pads. As is known in the art, bonding pads are used to permanently affix or bond wires or other thin conductors to the pad. Given the foregoing, and the fact that the Examiner has failed to lodge a *prima facie* obviousness rejection, the present ground of rejection is flawed and should be properly withdrawn.

Although Applicants consider Hirai non-analogous art and strenuously object to any rejection based *solely* on Hirai, the Examiner continues to utilize Hirai as a primary reference, to reject a variety of claims, in combination with four other individual references; namely, Hawkins et al., Damaschke et al., Saen et al., and Urushibata et al. For the reasons stated hereinabove, Applicants strenuously oppose the use of Hirai alone or in combination to reject any of the presently pending claims. Applicants strongly suggest that Hirai is an inapposite reference and cannot properly be applied against any of the pending claims.

Claims 42, 52, 62 and 76 stand rejected over Hirai in view of U.S. Pat. No. 6,029,089 to Hawkins et al. (Hawkins). Applicants again respectfully suggest that the Examiner has failed to comprehend that the "housing" element of the claimed subject matter comprises structure *underlying the bonding pads (or electrical connectors)*. Therefore, the teaching of Hawkins regarding use of "glass" on a "housing" to "provide visual confirmation of the electrical connection" not only fails to assert a *prima facie*



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obviousness rejection, it does not make sense in the context of the presently claimed invention. Indeed, herein claims 42, 52, 62 and 76 stand amended to include other materials recited in the specification; namely, ceramic material(s), and thermoplastic material(s). Surely these materials are not inherently capable of providing "visual confirmation." Because Hawkins (and Hirai for that matter) do not address, suggest, or motivate those of skill in the art to produce any structure even remotely similar to the claimed subject matter, this ground of rejection stands traversed and ought to properly be withdrawn.

Claims 55 and 66 stand rejected over Hirai in view of U.S. Pat. No. 6,351,884 to Damaschke et al. (Damaschke). Applicants repeat that Hirai is a non-analogous reference and simply is incapable of advancing any ground of rejection posed by the Examiner, particularly as a primary reference.

With to the secondary reference, Damaschke. First of all, Damaschke deals with manufacturing of printed circuit boards and not medical device technology. Second, claim 55 and claim 66 recite a welded union in the context of implantable medical devices. As previously stated, Hirai is devoid of any teaching regarding permanent connections within an IMD and offers no suggestion, motivation or other teaching to combine its teaching with any other teaching, much less the disclosure of printing circuit board manufacturing of Damaschke. For the above and foregoing reasons, Applicants respectfully assert that the Examiner has failed to lodge a *prima facie* obviousness rejection against claims 55 and 66 and as such, these claims are allowable over the art of record and the rejection should be withdrawn.

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Claims 57, 58, 68, and 69 stand rejected over Hirai in view of U.S. Pat. No. 4,870,227 to Saen et al. (Saen).

Saen apparently deals not with medical device technology but rather "spot-welding nickel-plated metal terminal[s]."

Herewith Applicants have amended claim 57 to delete the phrase "having at least one plating material." Likewise, claim 58 stands amended so that the materials recited relate to the "metal" and not any plating material. In similar fashion, claim 68 stands amended to delete the "plating material" limitation and insert in lieu thereof claim limitations regarding the shape of the electrical contacts ("geometrically shaped member") as supported by the specification. Finally, claim 69 stands amended to recite materials for the electrical contacts as supported in the specification ("a gold material, a nickel material and alloys of the gold material and the nickel material." Thus, the asserted combination, albeit deficient, has been rendered moot and should be withdrawn.

Claims 60, 61, and 63-68 stand rejected solely over Urushibata. First of all, Urushibata deals with a very narrow issue that is not present in the context of implantable medical devices. Second, the Examiner must exceed a considerable threshold when attempting to formulate a *prima facie* obviousness rejection using a *single reference*. As set forth in the "Field of the Invention:"

The present invention relates to a molded circuit component for connecting lead wires of round cross section to electric wires of flat cross section in domestic, industrial or motor vehicle internal wiring.

Thus, the reference appears not to relate to any of the issues confronted and addressed by the instant invention.

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Independent claim 60 stands amended herein to recite that the arrangement is used to establish permanent electrical communication between internal circuits of an IMD and at least one removeable remote electrical component. In addition, the Examiner is asked to refresh the understanding of the use of the term "housing" in the context of the presently claimed invention. As recited in independent claim 60, the housing is "disposed in sealing arrangement with said portion of the plurality of electrical contacts" and "further comprising a plurality of apertures for permanently receiving electrical wires for connection with the plurality of electrical contacts."

Applicants respectfully assert that these claim limitations clearly distinguish independent claim 60 from Urushibata. Since claims 61 and 63-68 also depend from claim 60 they too are clearly distinguished from Urushibata and the rejection should be withdrawn. Additionally, although claim 68 is cited as rejected *solely* over Urushibata, no rationale or other support was presented for the proposition. As such, the Examiner has clearly failed to lodge a *prima facie* obviousness rejection of claim 68 based on Urushibata and the rejection should be withdrawn.

Claim 62 stands rejected over Urushibata in view of Hawkins. Applicants hereby cross-reference and incorporate the above remarks regarding these two references as if fully set forth herein. In particular, the remarks regarding how inapposite Hawkins cannot be reasonably applied against the claims of the present invention. There is simply no claim regarding "visual confirmation of the electrical connection" anywhere in the present claim.

Claims 68 and 69 stand rejected over Urushibata in view of Saen, as applied above. Applicants hereby incorporate the prior remarks and arguments regarding these

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two references as if fully set forth herein. More particularly, as note hereinabove, claims 68 and 69 have been amended to eliminate the claim limitations regarding "plating metal" and, as such this ground of rejection is inapplicable and should be withdrawn.

Upon entry of this Reply, Applicants respectfully suggest that no other matters are outstanding and that all the various objections, informalities and rejections have all been addressed and the pending claims are now in condition for allowance. Applicants submit that the pending claims are patentably distinct over the cited references, as have been applied alone and in combination, and that all pending claims are in condition for allowance. Accordingly, Applicants requests that a Notice of Allowance be issued in due course so that the presently claimed invention may pass to timely issuance as U.S. Letters Patent. The Examiner is invited to contact the undersigned to discuss any aspect of the present application.

Respectfully submitted,

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By: Paul H. McDowall  
Reg. No. 34,873  
Telephone: (763) 514-3351  
Fax: (763) 514-6982  
Customer No. 27581